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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09 732,411	12 07 2000	Samy Ashkar	CMZ-124CP	1508

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LAHIVE & COCKFIELD
28 STATE STREET
BOSTON, MA 02109

EXAMINER

HADDAD, MAHER M

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 02 05 2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/732,411

Applicant(s)

ASHKAR, SAMY

Examiner

Maher M. Haddad

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-29 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) ____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other See Continuation Sheet

Continuation of Attachment(s) 6). Other: Fax Transmission Restriction Election.

Art Unit: 1644

DETAILED ACTION

Sequence Compliance

1. The instant application appears to be in sequence compliance for patent applications containing nucleotide sequence and/or amino acid sequence disclosures.

Restriction Requirement

2. Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Paula Hutzell, Ph.D., Supervisory Patent Examiner at Paula.Hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

3. The following is noted:

- A) Independent Claims 1 and 20 include a recitation of "modulating adhesion of a target cell to a substrate" or "an adhesion modulatory peptide". Dependent claims 3, 11 and 22 recite that modulating is "inhibits adhesion", whereas dependent claims 2, 10 and 21 recite that modulating is "enhances adhesion". These methods are mutually exclusive in that they reach opposing endpoints, and in that they employ structurally distinct "peptide" to accomplish these mutually exclusive endpoints.

Consequently, the claims have been limited to either a method of *inhibiting adhesion*, or a method of *enhancing adhesion*, irrespective of the format of the claims.

- B) The specification discloses that SEQ ID NOS: 1-15 and SDV peptide each differ with respect to their structure, physiochemical properties and function (pages 9 and 10, table II). Although each peptide is proposed to be an adhesion-modulatory peptide, the specification indicates that individual peptides have different functions and widely vary in their size and composition. A person of ordinary skill in the art thus would not envision one peptide in the view of the other. Consequently, because the polypeptide of each SEQ ID NO is structurally distinct, the restriction has been set forth for each as separate groups, irrespective of the format of the claims.

Art Unit: 1644

4. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I-XVI. Claims 1-2, 4-10, and 12-19, drawn to a method of enhancing adhesion of a target cell to a substrate comprising an amino acid SEQ ID NO: 1-15 and SDV peptide, classified in Class 514, subclass 2.

XVII-XXXII. Claims 1, 3 and 4-9, 11-19, drawn to a method of inhibiting adhesion of a target cell to a substrate comprising an amino acid SEQ ID NO: 1-15 and SDV peptide, classified in Class 514, subclass 2.

XXXIII-XLVIII. Claims 20-29, drawn to an adhesion modulator peptide, a substrate, a device, and a composition comprising SEQ ID NO: 1-15 and SDV peptide, and a carrier, classified in Class 530, subclasses 300.

5. Groups I- XXXII are different methods. A method of enhancing and a method of inhibiting adhesion differ with respect to ingredients, method steps, and endpoints; therefore, each method is patentably distinct.

6. Groups XXXIII-XLVIII, and I- XXXII are related as product and process of using. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the peptides of Groups XXXIII-XLVIII can be used as an antigen for the production of antibodies, in addition to the methods of enhancing and inhibiting adhesion recited.

7. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by different classification and/or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the structurally distinct products recited and the various methods of use comprising distinct method steps. Therefore restriction for examination purposes as indicated is proper.

Art Unit: 1644

Species Election

8. This application contains claims directed to the following patentably distinct species of the claimed Inventions I- XXXII: wherein the target cell is:

- A) endothelial,
- B) fibroblast,
- C) macrophage,
- D) neutrophil, or
- E) myofibroblast.

These species are distinct because their modes of action are different.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

9. This application contains claims directed to the following patentably distinct species of the claimed Inventions I- XLVIII: wherein the substrate is:

- A) a polyvinyl surface,
- B) a gel,
- C) collagen,
- D) hyaluronic acid,
- E) titanium,
- F) PGA, or
- G) others recited on page 3 of the specification.

These species are distinct because their structure and modes of action are different.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

10. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Art Unit: 1644

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

11. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maher Haddad whose telephone number is (703) 306-3472. The examiner can normally be reached Monday through Friday from 8:00 AM to 4:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Maher Haddad, Ph.D.
Patent Examiner
Technology Center 1600
February 1, 2002

Phillip Gambel
PHILLIP GAMBEL, PH.D
PRIMARY EXAMINER
TC 1600
2/4/02